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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,344	04/19/2001	Claudine Guerin-Marchand	010830-116	2865

7590 11/12/2003

EXAMINER
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ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/837,344	GUERIN-MARCHAND ET AL.	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-38* is/are pending in the application.

4a) Of the above claim(s) *27-30,33,34 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31,32 and 35-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *27-30,33,34 and 38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) 3 sheets
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4/19/01
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election with traverse of Group II, claims 31-38 and species election of SEQ ID NO: 41, in Paper No. 13 is acknowledged. The traversal is on the ground(s) that the restriction requirement is improper because at least the search and examination of all the pending claims can be made without serious burden, particularly so in light of the clearly close relationship between the subject matter of Groups I and II. Applicants also traverse the species election. Applicants believe that the claims based on SEQ ID NO: 41 should be considered together with those claims based on SEQ ID NO: 45, as can be seen from the sequence listing of the present application, the amino acid sequences of SEQ ID NO: 41 and SEQ ID NO: 45 differ only in position 277. This is not found persuasive because the restriction Groups have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. A reference, which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other groups. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist.

It is noted that Applicants reserve the right to rejoin the claims of Group I, drawn to a process of using the elected polypeptides of Group II, at such time

when the elected polypeptide claims of Group II are found allowable. MPEP 821.04

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 27-30, 33, 34 and 38 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

3. Claims 31, 32, and 35-37 will be examined.

4. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or

REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)

(e) BACKGROUND OF THE INVENTION.

(1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) BRIEF SUMMARY OF THE INVENTION.

(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(h) DETAILED DESCRIPTION OF THE INVENTION.

(i) CLAIM OR CLAIMS (commencing on a separate sheet).

(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

5. Claims 31, 32 and 35-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a polypeptide comprising at least one T epitope or B epitope from a liver-stage specific protein produce by *P. falciparum*, and vaccine compositions comprising the polypeptide. The claims also recite that the T epitope has an amino acid sequence of SEQ ID NO: 41.

The specification does not specifically define the T epitope or the B epitope from a liver-stage specific protein produced by *P. falciparum*. The specification does not define any amino acid sequence of any epitope, T or B, as it relates to

SEQ ID NO: 41, which set forth an amino acid sequence of 493 residues. The specification does not indicate where any of the T epitopes or B epitopes from a liver-stage specific protein produced by *P. falciparum*, and compositions comprising the polypeptide, save those discussed for SEQ ID NO: 23, 24, 26-28 and 31. The specification does not provide any information regarding T epitopes or B epitopes in the protein of SEQ ID NO: 41. The specification indicates that these sequences contain at least one T epitope or B epitope from liver-stage specific proteins produced from P. falciparum. The specification does not set forth the relationship of SEQ ID NO: 23, 24, 26-28 and 31 with claimed SEQ ID NO: 41. It is not clear how many T epitopes and how many B epitopes are in a liver-stage specific protein, nor how many of these epitopes are found in SEQ ID NO: 41. The critical T epitope or B epitope characteristics have not been taught in the specification for elected species SEQ ID NO: 41. The specification at page 25 sets forth the Construction of Genomic DNA Library and page 26 sets forth Immunological Screening of Bank. The specification does not enable a polypeptide comprising at least one T epitope or B epitope from a liver-stage specific protein produce by *P. falciparum*, and vaccine compositions comprising the polypeptide and where the epitopes are defined in SEQ ID NO: 41.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214

USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 31, 35 and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6319502. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the patent and pending application claim and/or disclose a polypeptide comprising at least one T epitope or B epitope from a liver-stage specific protein produce by *P. falciparum*, and compositions comprising the polypeptide.

8. Claims 31, 35 and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5690941. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the patent and pending application claim and/or disclose a polypeptide comprising at least one T epitope or B epitope from a liver-stage specific protein produce by *P. falciparum*, and compositions comprising the polypeptide.

9. Claims 31, 35 and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 7 of U.S. Patent No. 5599542. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the patent and pending application claim and/or disclose a polypeptide comprising at least one T epitope or B epitope from a liver-stage specific protein produce by *P. falciparum*, and compositions comprising the polypeptide.

10. Claims 31, 35 and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6270771. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the patent and pending application claim and/or disclose a polypeptide comprising at least one T epitope or B epitope from a liver-stage specific protein produce by *P. falciparum*, and compositions comprising the polypeptide.

11. Claims 31, 32 and 35-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 and 25 of copending Application No. 09/900963. Although the conflicting claims are not identical, they are not patentably distinct from each other because both pending applications claim and/or disclose a polypeptide comprising at least one T epitope or B epitope from a liver-stage specific protein produce by *P. falciparum*, as well as vaccine compositions comprising a polypeptide comprising at least one T epitope or B epitope from a liver-stage specific protein produce by *P. falciparum*.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 31, 32 and 35 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The product, as claimed, has the same characteristics and utility as that found in nature. To overcome this rejection the Examiner suggests the amendment of the claims to include purity limitations, which would distinguish the characteristics and utility of applicant's product as enabled in the specification from the utility of the product as it exists in nature. It is further suggested that such limitation include the terminology "essentially purified and isolated" (i.e. if such purity is supported in the specification) and/or a description of what applicant's protein is "free of" relative to the natural source, which imparts a distinct utility to the claimed product. For relevant case law see Farbenfabriken of Elberfeld Co. v. Kuehmsted, 171 Fed. 887, 890 (N.D. Ill. 1909) (text of claim at 889); Parke-Davis & Co. v. H.D. Mulford Co., 189 Fed. 95, 103, 106, 965 (S.D.N.Y. 1911) (claim 1); and In re Bergstrom, 427 F.2d 1394, 1398, 1401-1402 (CCPA 1970).

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 31, 35 and 36 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Londono et al 1990 (J. Immunol., 145/5:1557-1563, abstract only) or Guerin-Marchand et al 1987 (Nature, 329/6135:164-167).

The claims are directed to a polypeptide comprising at least on T epitope or B epitope from a liver-stage specific produced by a *P. falciparum* and a

composition comprising said polypeptide comprising at least one T epitope or at least one B epitope from a liver-stage specific produced by a *P. falciparum.*

Londono et al discloses composition that comprises polypeptides that have both B and T cell epitopes from antigens of P. falciparum (abstract).

Guerin-Marchand et al disclose polypeptides that comprise a single 17 amino acid repeat that has at least one epitope and that the protein is a liver-stage specific antigen (abstract).

It is noted that the recitation of "vaccine" in claim 36 is viewed as intended use. The recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Since the Patent Office does not have the facilities for examining and comparing applicants' polypeptides with the polypeptides of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed polypeptides and the polypeptides of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

17. No claims are allowed.

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
September 30, 2003